JUL 2 9 2002

K021881

Section 7 - 510(k) Summary

7.1 Statement

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Endius, Inc. is required to submit with this Premarket Notification either an "... adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." Endius, Inc. chooses to submit a summary of information respecting safety and effectiveness. According to §513(i)(3)(B), "Any summary under subparagraph (A) respecting a device shall contain detailed information regarding data concerning adverse health effects..."

The summary regarding the adverse health effects of the modified device, Endius® TiTLE™ Spinal Fixation System is provided below.

7.2 Submitter

Endius, Inc.
23 West Bacon Street
Plainville, MA. 02762

7.3 Company Contact

Christine Kuntz-Nassif
Director, Regulatory Affairs
508-643-0983 Ext. 114

7.4 Device Name

Proprietary Name:
Endius® TiTLE™ Spinal Fixation System
Common Name:
Pedicle Screw System , Non-pedicle spinal fixation system
Classification Name:
Spinal Pedicle Screw (MNI),Spinal Interlaminal fixation orthosis (KWP), Spondylolithesis Spinal Fixation Device System (MNH)

7.5 Predicate Device	Endius Spinal Fixation System: K014090	Page 2 of 2
7.6 Device Description	The Endius® TiTLE™ Spinal Fixation System is a system that is intended to be used for posterior lumbar fusion procedures. The system is manufactured from titanium which complies with ASTM F136. The components, which are included as part of the system, include screws, rods, and connection components.	
7.7 Device Indications and Intended Use	The Endius® TiTLE™ Spinal Fixation System is indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Levels of fixation are for the thoracic, lumbar, and sacral spine. The Endius® TiTLE™ Spinal Fixation System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The Endius® TiTLE™ Spinal Fixation System is also indicated for pedicle screw fixation for severe spondylolithesis (grades 3 and 4) at L5-S1, in skeletally mature patients, when autogenous bone graft is used, when affixed to the posterior lumbosacral spine, and intended to be removed after solid fusion is attained. Levels of fixation are from L3-S1. In addition, the Endius® TiTLE™ Spinal Fixation System, when not used with pedicle screws is indicated for hook, wire, and/or sacral screw fixation from T1 to the ilium sacrum. The non-pedicle screw indications are spondylolithesis, degenerative disc disease, (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), deformities (scoliosis, lordosis and kyphosis), tumor, fracture, and previous failed fusion surgery.	
7.8 Substantial Equivalence	The proposed Endius TiTLE Spinal Fixation System is substantially equivalent to the Endius Spinal Fixation System.	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 9 2002

Christine Kuntz-Nassif
Director, Regulatory Affairs
Endius, Inc.
23 West Bacon Street
Plainville, MA 02762

Re: K021881
Trade/Device Name: Endius® TiTLE™ Spinal Fixation System
Regulation Number: 21 CFR 888.3050, 888.3070
Regulation Name: Spinal interlaminal fixation orthosis; spondylolisthesis spinal fixation device system; pedicle screw spinal system
Regulatory Class: Class II, III
Product Code: KWP, MNH, MNI
Dated: June 3, 2002
Received: June 7, 2002

Dear Ms. Kuntz-Nassif:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K021881

Device Name: Endius® TiTLE™ Spinal Fixation System (Titanium)

Indications for Use:

The Endius® TiTLE™ Spinal Fixation System is indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies). Levels of fixation are for the thoracic, lumbar, and sacral spine.

The Endius® TiTLE™ Spinal Fixation System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

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In addition, the Endius® TiTLE™ Spinal Fixation System, when not used with pedicle screws is indicated for hook, wire, and/or sacral screw fixation from T1 to the ilium sacrum. The non-pedicle screw indications are spondylolithesis, degenerative disc disease, (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), deformities (scoliosis, lordosis and kyphosis), tumor, fracture, and previous failed fusion surgery.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Posted July 1, 1998)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021881